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204245/2094

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Clive Elson et al.

Serial No.:

10/810,742

Filed:

March 25, 2004

Titled:

N-acylated chitinous polymers and

methods of use thereof

Examiner:

Everett White

Group Art Unit:

1623

Conf. No.:

9666

CERTIFICATE OF MAILING UNDER 37 CFR 1.10

I hereby certify that the paper (and any paper or fee referred to as being enclosed) is being deposited with the United States Postal Service using Express Mail to Addressee Service, under 37 C.F.R. Section 1.10, Express Mail Label No. EV 970 591 026 US on this date August 13, 2007, postage prepaid, in an envelope addressed to Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Declaration under U.S.C. 1.132

- 1. I, Susan E. Henderson, a citizen of 197 Hawthorne St., Dartmouth, Nova Scotia, CANADA, B2Y 2Z1, declare the following:
- 2. I am an inventor noted on the instant application.
- 3. I have read and reviewed the rejection under 35 U.S.C. § 102(b) applied in the Office Action mailed from the USPTO on March 19, 2007, in which claims 1-8 and 11-19 are rejected as being anticipated by Elson (U.S. Patent 5,888,988).
- 4. I understand the Examiner has applied the rejection on the basis that U.S. Patent 5,888,988 discloses an embodiment of the N-acylated chitinous polymer as previously claimed.
- 5. I understand that the claims as newly amended require that the instantly claimed N-acylated chitinous polymer have a degree of carboxylation from the carboxymethyl group that is lower than the degree of carboxylation from the R, e.g., succinate, group.
- 6. Presented in the above referenced patent application is a working example, Example 2, teaching a method of synthesis of N,O-carboxymethyl-N-succinylchitosan (NS—NOCC)

starting from chitosan. The first step describes the N-succinylation of chitosan, in which the yield of N-succinylchitosan had a degree of succinylation of 0.9. The second step describes the carboxymethylation of N-succinylchitosan to produce the claimed N-acylated chitinous polymer. In this method of synthesizing N,O-carboxymethyl-N-succinylchitosan (NS—NOCC) starting from chitosan as illustrated by this example, the total degree of carboxylation is 1.2-1.3. Thus the N-acylated chitinous polymer has a degree of carboxylation from the carboxymethyl group (0.3-0.4) that is lower than the degree of carboxylation from the R group (0.9).

- 7. The N-acylated chitinous polymer taught by Elson in U.S. Patent 5,888,988, which was made through the succinylation of NOCC, has a degree of carboxylation from the carboxymethyl group that is higher than the degree of carboxylation from the R group. The degree of carboxylation from the carboxymethyl group is about 0.8-0.9, and the degree of carboxylation from the R group is about 0.3 succinyl groups per sugar, yielding a total carboxylation of about 1.3.
- 8. The steps used to generate the data consisted of the following:

for synthesis N,O-carboxymethyl-N-succinylchitosan, from NOCC.:

- (a) 15 kilograms of water solution containing 150 grams of a high viscosity NOCC was stirred as 105 grams of succinic anhydride was added over 30 minutes at room temperature. The pH was maintained between 7-9. The reaction was allowed to proceed for 2.5 hours.
- (b) The mixture was added to 40 liters of anhydrous isopropanol and the resulting precipitate was collected by filtration. The product was washed 3 times in 80% methanol/water and then air-dried. The yield was 186 grams.
- (c) The product was a white, totally soluble solid with a viscosity of 900 cps for a 1% solution (Brookfield, spindle #4, 20C) and having an ash of 23.4%.
- (d) The degree of carboxylation was 1.3.
- (e) The degree of succinylation is 0.3.

<u>Conclusion</u>: The N,O-Carboxymethyl-N-Succinylchitosan taught by Elson (U.S. Patent 5,888,988) has a degree of succinylation is 0.3.

The above data supports the conclusion that the N-acylated chitinous polymer taught by Elson in U.S. Patent 5,888,988, which was made through the succinylation of NOCC, has a degree of carboxylation from the carboxymethyl group which is higher than the degree of carboxylation from the R group; and thus does not fall under the scope of claim 1 as amended, and its dependent claims, which requires that the instantly claimed N-acylated chitinous polymer have a degree of carboxylation from the carboxymethyl group that is lower than the degree of carboxylation from the R group.

All statements made herein of my own knowledge are true, and all statements made on

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information and belief are believed to be true, and these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application and any patent issuing thereon.

Susan E. Henderson . Jusan J. Henderson

Date: August 8, 3007